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SAFETY MARGINS IN THE IMPLEMENTATION

OF

PLANETARY QUARANTINE REQUIREMENTS

INTERIM REPORT

Contract NASw-2062

National Aeronautics and Space Administration
Planetary Quarantine Office
Washington, D.C. 20546

by

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I. INTRODUCTION

The formulation of planetary quarantine requirements, and their imple-
mentation, rest on a risk allocation model in which risk is defined in terms of the
probabilities of the various events which can lead to planetary contamination.
Until recently, risk allocation procedures were limited to the following:

COSPAR: Recommends an upper bound for the proba-
bility that the planet will be contaminated
for an assumed (estimated) number of mis-
sions and stated period of time, e.g.,
$P_c = 10^{-3}$.

NASA: Specifies an upper bound for the probability
that a particular flight mission will contami-
nate the planet.

FLIGHT PROJECT: Allocates to flight elements an upper bound
probability of contamination.

At the flight project level, implementation of the upper bound con-
straints involves an analysis of individual contamination sources, e.g., micro-
organisms contained within spacecraft materials, so as to define the precautions,
such as heat sterilization, which will assure that the allocated upper bound will
not be exceeded. A central aspect of this implementation procedure is the esti-
mation of individual parameters, such as the mean number of organisms associated
with the contamination source, the probability that they will be released onto the
planet surface, the probability that they will survive and proliferate on the planet,
etc. Clearly, the degree of conservatism applied to the estimation of these

individual parameters will affect the severity of precautionary measures to be applied, e.g., the length of required heat sterilization cycles. Conversely, this process also determines the safety margin, or confidence, in the attainment of the specified upper bound probability that the source under consideration will contaminate the planet.

The 1970 COSPAR meeting focused on these safety margins in the implementation of Planetary Quarantine requirements. For, at this meeting, it was noted that the various parameters used to determine the probability of contamination are random variables which must be estimated. As any estimation procedure has its associated errors, attention was focused on the effect of these errors on the implementation process.

These considerations resulted in the following recommendation by the COSPAR Panel on Planetary Quarantine (Leningrad, May 1970):

"... the Panel wishes to call to the attention of COSPAR the desirability of improving the contamination model ... Recognizing that setting errors of estimation for the several relevant terms of the equation may be very difficult, the Panel notes:

a. Without estimating errors and their propagation one cannot defend the assumption that the overall chance of planetary contamination is in fact the value assigned.

b. A conscientious attempt to estimate all error terms will surely reveal specific sites of uncertainty better than can be done intuitively and indicate where renewed effort is warranted.

The Panel recommends that the equation referred to as the contamination model be up-dated by inclusion of error terms."

This report summarizes work performed by Exotech Systems, Inc. relating to the implementation of the above COSPAR recommendations. A number of

alternatives are examined herein, with particular emphasis on their utility in achieving the desired minimization of excessive safety margins on the one hand, and their effect on implementation procedures, on the other.

2. BACKGROUND

To facilitate discussion of the considerations involved in defining and controlling safety margins, we will consider an illustrative source of contamination, viz., microorganisms contained (buried) within spacecraft materials. Current analyses of this contamination source is performed in terms of the following relationship:

$$m_B(0) \cdot 10^{-t_B/D_B} \cdot P_B(r) \cdot P_G \leq A_B \qquad (1)$$

where:

A_B Allocation of mission contamination probability to buried load

$m_B(0)$ Number of viable microorganisms prior to sterilization (at $t_B = 0$)

t_B Number of hours of heat sterilization

D_B Resistance of microorganisms to heat sterilization

$P_B(r)$ Probability that a buried organism will be released on planet surface in a viable state

P_G Probability that a released organism will cause proliferation of terrestrial biota on Mars.

A_B is a specified constraint, derived from a suballocation of the mission contamination probability to the various contamination sources. The parameters on the left hand side must be estimated in order to specify the required sterilization time, t_B, which will assure attainment of the allocation A_B.

The illustrative contamination source of equation (1) can be generalized to represent all sources of contamination encountered in the implementation process. This would take the form

$$10^N \cdot 10^{-CE} \cdot 10^{-AE} \, 10^{-G} \, 10^{-C} \leq 10^{-A} \qquad (2)$$

As noted above, all parameters are shown as exponents of 10, consistent with the manner in which they are generally estimated or assigned. The individual parameters may be amplified as follows:

(a)   Initial Microbial Population — 10^N

The basic source of contamination is, of course, the initial microbial contamination associated with the source before the application of decontamination or sterilization controls. In equation (1) $10^N = m_B(0)$.

(b)   Conditional Events — 10^{-CE}

In most instances, the threat of contamination by a microbial population is conditional on the occurence of some events. Associated with these conditional events is the probability 10^{-CE}. In the preceding illustration, $P_B(r)$ is such a conditional event for a microorganism contained within materials can not contaminate the planet unless it is released in viable form onto the planet surface.

(c)   Attenuating Events — 10^{-AE}

Although not included in the preceding illustration, some contamination sources may be subjected to destructive environments, such as exposure to uv radiation, before arrival at the planet. Such events would reduce (attenuate) the initial microbial burden. This reduction can be accounted for through the probability 10^{-AE} that any one organism would survive the attenuating environment.

(d)   Probability of Growth and Proliferation — 10^{-G}

This term is identical to P_G as previously defined.

(e)   Controls — 10^{-C}

Current practice utilizes the logarithmic reduction model to describe the effect of sterilizing environments. In such instances $10^{-C} = 10^{-t/D}$. More generally, 10^{-C} represents the controls applied to the initial population so as to reduce it to a level consistent with the allocation 10^{-A}.

The estimation of individual parameters involves varying degrees of uncertainty concerning the value to be used. In general, a parameter estimator may be viewed as having a distribution of values and the problem is that of first establishing this distribution and then selecting a value within the distribution which best serves the purpose of achieving the constraint with the desired confidence.

An evaluation by an ad hoc committee of the Space Science Board in July of 1970 of the parameter P_G for Mars will serve to illustrate the process and

difficulties of this estimation procedure. The findings of the Space Science Board were summarized by the ad hoc Review Group and presented to NASA (December 1970) as follows:

| | 0.999 Confidence Factor— |
Even Odds Estimate	Upper Limit Estimate
P_G: 3×10^{-9}	1×10^{-4}

The report then states:

"Predictably, the estimate of the probability of growth increases significantly with the requirement for high confidence in the individual estimates. This change is largely a reflection of our lack of knowledge of the Martian surface environmental conditions. In view of these uncertainties the review group recommends that NASA use the value of $P_G = 1 \times 10^{-4}$ for its spacecraft sterilization allocation model, at least until further data from planetary flights justify a re-evaluation. However, NASA should also recognize the conservative nature of this value for P_G when considering safety factors in the estimation of other sterilization parameters, so as to avoid excessive safety margins in the implementation of planetary quarantine requirements."

Since P_G necessarily appears in the analysis of all contamination sources, the above recommendation offers one possible approach to the control of safety margins. Its implementation requires use of the conservative value $P_G = 10^{-4}$ and a less conservative value in the estimation of the other parameters in equation (1). It remains, however, to be specified what is a less conservative value. Is it the .50 confidence value or the 0.85 confidence value? Thus, it is still necessary to deal with a distribution of values and to select one among them consistent with the desired limits on the overall safety margin.

An important precedent established in the above evaluation of P_G was that of estimating two limiting values of the parameter in terms of the associated confidence factors. To generalize on this approach it would be necessary to clarify the following two areas:

(1)   a uniform understanding of the two boundary confidence values, e.g., 0.999 and 0.50, should be established in order that the various experts called upon to estimate parameter values may approach the task of combining factual and judgmental considerations in a uniform manner, and

(2)   the shape of the distribution needs to be defined to permit the selection of a parameter value for confidences other than the boundary confidence values used in the estimation process.

The above considerations are further developed below.

3. ANALYTICAL BASIS FOR SINGLE PARAMETER CONFIDENCE

As noted earlier, the parameters to be estimated, or to be controlled, take the form 10^x. The estimation procedure therefore involves the assignment of a suitable value to the exponent x. From a practical point of view, it is adequate to restrict our consideration to the absolute value of x, i.e., $|x|$, since the polarity to be assigned derives directly from the parameter under consideration, e.g., it is negative for a probability and positive for a microbial

load. Since a probability cannot be larger than unity and because a microbial load less than unity is of no practical interest, $x \gtrless 0$ represents the entire range of interest. It is also desirable to use a non-symetric distribution so as to aggregate more of the area under the curve toward the smaller values of $|x|$, i.e., in the conservative range of the probabilities to be estimated. These considerations, and the desire for analytical simplicity, lead to the choice of a log-normal distribution of $|x|$.

Figures 1a and 1b show families of log-normal density functions, illustrating the shapes which can be generated by suitable choices of the mean, μ, and standard
will be fully defined if two points are known. The key problem is, therefore, to identify two values of $|x|$ in a manner which is both amenable to estimation and relatable to the selected distribution function.

The procedure for estimating the value of a parameter generally involves two discrete steps. First, it is desirable to identify as much baseline data as is possible, even though such data may apply only to a small sub-set of the conditions of interest. For example, in estimating the probability of microbial release from materials as a result of fracture at high impact velocities, it is useful to obtain quantitative data from laboratory experiments concerning the degree to which some specific materials fracture when impacting on selected surfaces at a range of known velocities. Such data is quantitative and, for the laboratory conditions, contains relatively little uncertainty. The problem arises in the next step which requires the extrapolation of this data to a wide range of application conditions, with considerable uncertainty in the definition of the applicable range as well as in the validity of the extrapolated data. In the preceding example, the uncertainties would relate to the types of materials which would be contained on an actual spacecraft

(which is clearly greater than that used in laboratory experiments), the types of impact surfaces which might be encountered, the range of impact velocities and their probabilities of occurrence, etc.

The above estimation process is clearly one of combining facts with judgments. The distribution function of $|x|$ therefore attempts, in this application to describe values of $|x|$ in terms of the likelihood that the estimation process reflects the "true" conditions. The shape of the probability density curve is therefore heavily influenced by such consideration as the relative amount of applicable factual vs juegmental inputs and even the choice of individuals to provide the expert judgment.

In applying expert judgment it is not unreasonable to ask an individual to state an "even-odds" estimate of a parameter value. Such an estimate might also be arrived at as a consensus even-odds value of a group of experts, provided they are not of diverse disciplines and therefore avoid the application of safety margins deriving largely from lack of detailed familiarity with the subject matter. Such an even-odds value is readily relatable to the distribution function, for it can be associated with the 50% confidence value, i.e., the value of $|x|$ for which the area under the curve is divided in two equal parts. This value of $|x|$ will be denoted as M, and represents the median value of $|x|$.

Under conditions of uncertainty it is desirable to also obtain a boundary value which might represent "worst case" conditions. The bound of $|x| = 0$ is clearly available but is not very useful. Thus, a high confidence value is often sought, e.g., a 0.999 or 0.99 confidence estimate. Considering the subjective nature of the estimation process it is difficult to define the exact meaning of a specific confidence value. Tenuous as this may be, though, it is nevertheless possible to arrive at such a value in a workable manner.

Referring again to the single, or group, of experts charged with the task of selecting a high confidence, or adverse value of $|x|$, the process generally involves considering decreasing values of $|x|$ until there is a break in credibility that it could be much smaller than that. Referring to Figure 2 of a typical log-normal distribution function, the value of $|x| = M_A$ represents such a point, for it corresponds to the knee in the curve, beyond which the curvature becomes flat, suggesting relatively small likelihood for values of $|x|$ smaller than M_A. This value, M_A, also approximates the 0.99 confidence estimate, for the area under the curve to the right of M_A is on the order of 99% of the entire area. (The 0.999 confidence value would, on the other hand, be on an otherwise undefinable part of the flat portion of the curve, to the left of M_A.)

The median (0.5 confidence) and adverse (0.99 confidence) values are sufficient to define the entire log-normal distribution. It is then a straight-forward process to compute any other confidence value of $|x|$ from

$$x(c) = M \left(\frac{M_A}{M} \right)^{\frac{K(c)}{2.33}} \tag{3}$$

where
$x(c)$ is the value of $|x|$ at the desired confidence level, c, e.g., c = .75

$K(c)$ is the quantile of the standard normal distribution corresponding to the desired value of c

M_A = x(0.99)

M = x(0.50)

For convenience, equation (3) has been plotted in Figure 3 for different values of M_A/M.

Figures 1a and 1b illustrate the shapes of the distribution which result from different values of M and M_A. Figure 1a shows the effect of uncertainty in the estimating process as reflected by changes in the ratio of M/M_A (assuming M = 1 in all instances). Thus, as the spread between the median and adverse value increases, i.e., as M/M_A increases, the distribution becomes more skewed toward the conservative region (near zero). The effect of increasing values of M for a fixed value of M/M_A is illustrated in Figure 1b.

It is of interest to quantitatively evaluate the choice of a 0.99 confidence as the basis for an adverse estimate of the parameter. Assume, for example, that a probability is being estimated with the result that the median is taken to be 10^{-4} and the adverse value 10^{-2}. This implies M = 1 and M_A = 2. Further assume that an 85% confidence value is desired based upon the above. Using the log-normal procedure described herein, $x(0.85)$ = 3.02. At 85% confidence the value of the probability would therefore be $10^{-3.02}$.

The above is based on M_A being the 0.99 confidence value of the exponent. How much difference would it have made if M_A = 2 where taken as the 0.999 confidence value? As can readily be calculated, the 85% confidence value in this instance would have been 3.25 rather than 3.02. Whether M_A is considered to be the 0.99 or 0.999 confidence value is, therefore, not too significant from a quantitative point of view. However, associating M_A with a 0.99 confidence value, in the sense that it represents a point of inflection in the distribution fraction, facilitates the subjective estimation process.
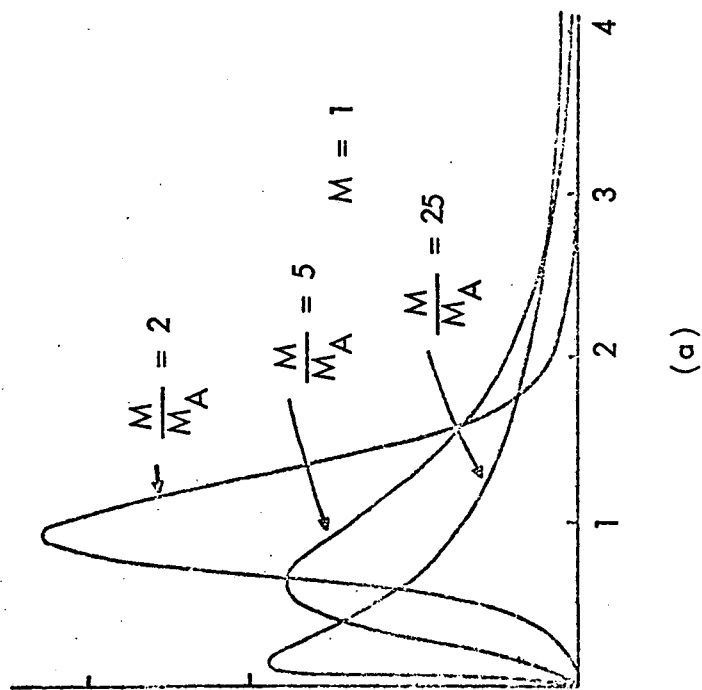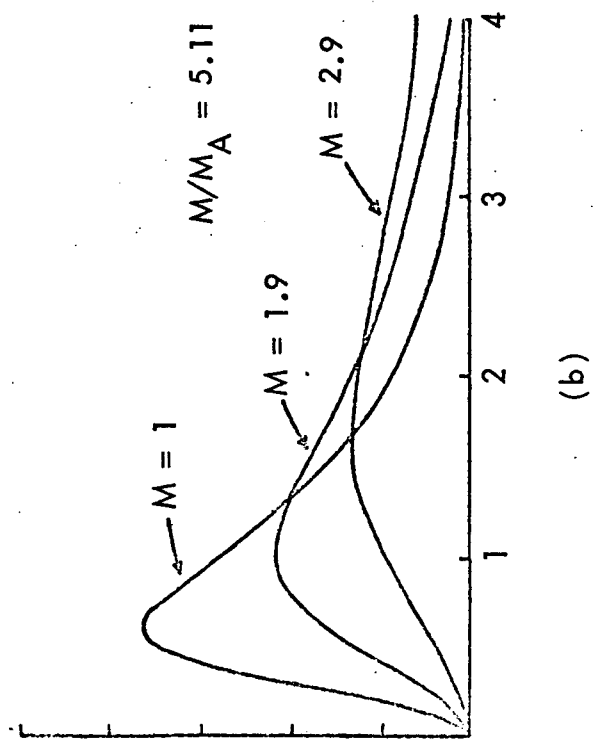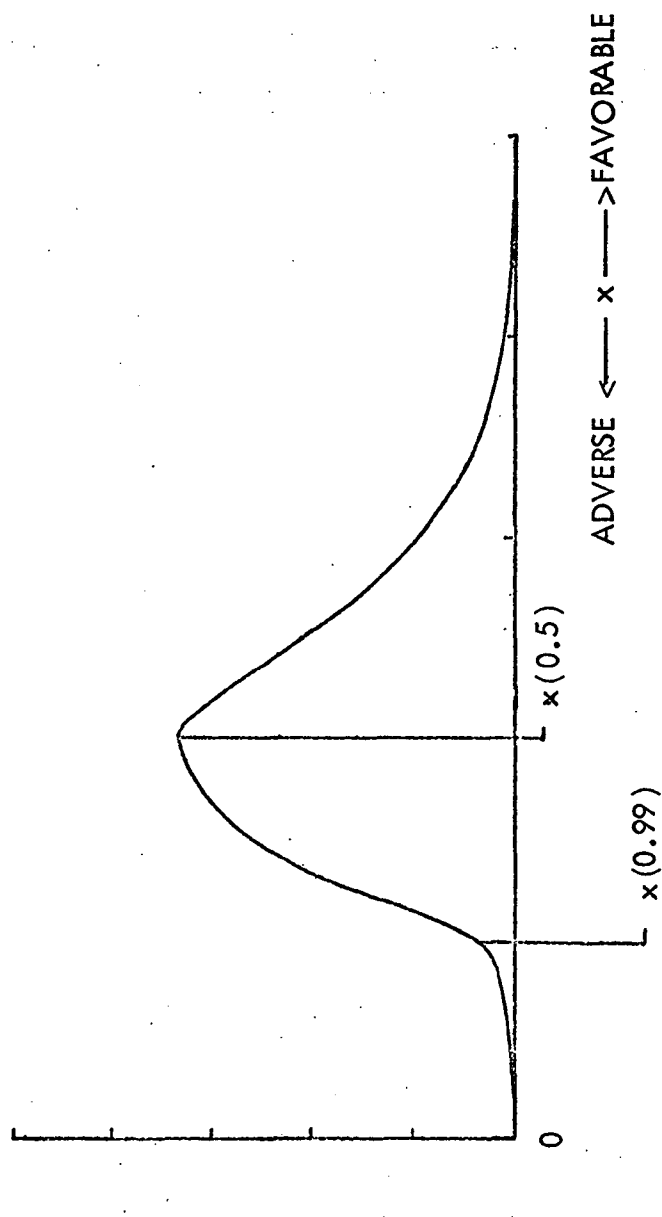
Figure 1: Log-Normal Distribution

x(0.5) — Median (M) Value of x

x(0.99) — Maximum Adverse (M_A) Value of x

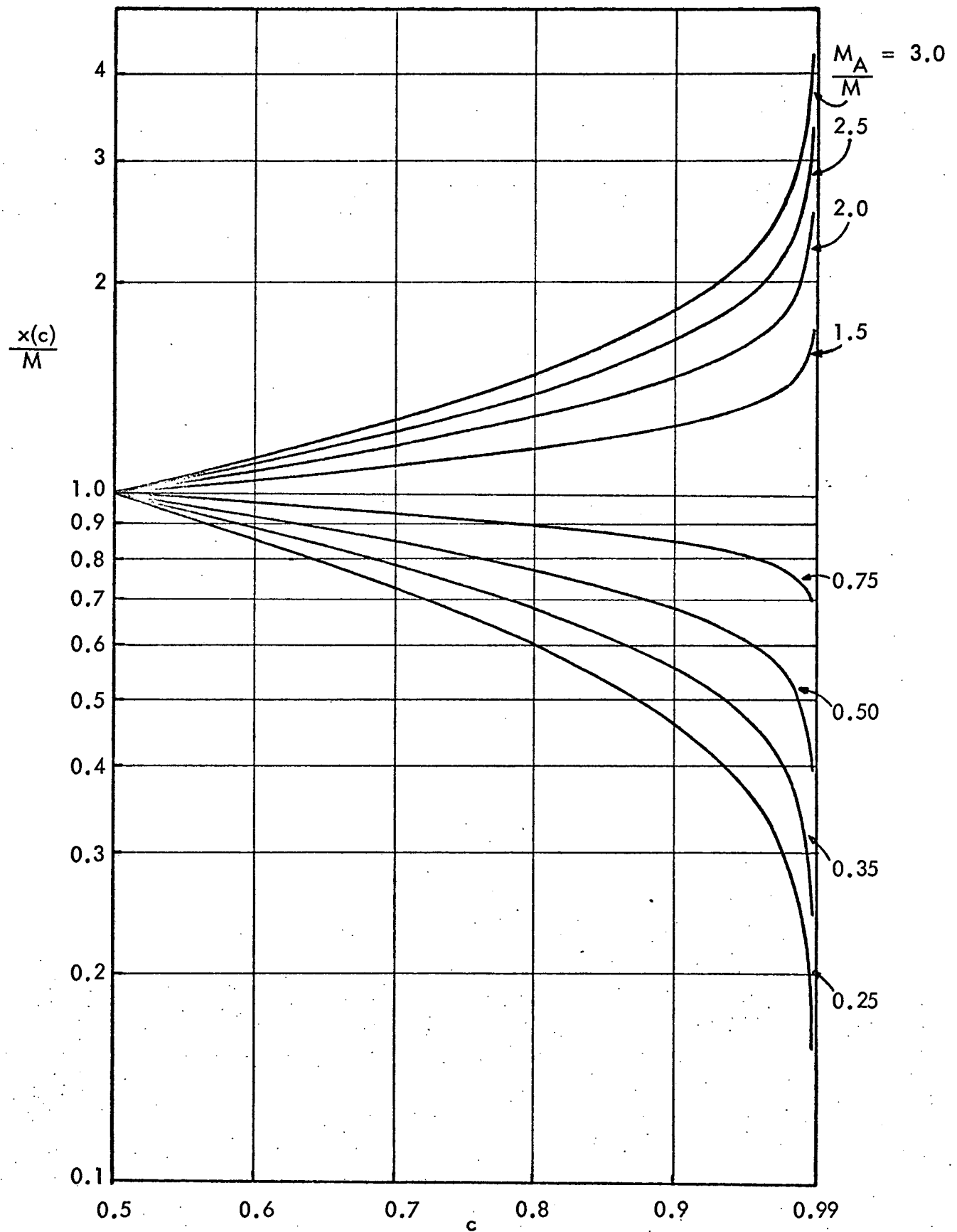Figure 2: Typical Log–Normal Distribution Function for x(c).

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Figure 3. Estimate of x as a Function of Confidence c

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4. ANALYTICAL BASIS FOR COMBINED PARAMETER CONFIDENCE

Referring again to equation (2), it is of interest to relate the distribution of the parameters on the left hand side, to the distribution of the allocation 10^{-A}. More specifically, it is desirable to relate the "confidence" with which the allocation is attained to the manner in which the individual parameters in the contamination source are estimated. From an analytical point of view, these questions are most readily evaluated if it is assumed that each parameter, 10^{x_i}, is log-normally distributed, i.e., the exponent x_i is assumed to be normally distributed with mean μ_i and variance σ_i^2. For it then follows that the allocation A would also be normally distributed and readily relatable to the means and variances of the individual distributions. Specifically,

for $\qquad 10^N \qquad\qquad N \sim N\left(\mu_N, \ \sigma_N^2\right)$

for $\qquad 10^{-CE} \qquad\quad CE \sim N\left(\mu_{CE}, \ \sigma_{CE}^2\right)$

for $\qquad 10^{-AE} \qquad\quad AE \sim N\left(\mu_{AE}, \ \sigma_{AE}^2\right) \qquad\qquad$ (4)

for $\qquad 10^{-G} \qquad\qquad G \sim N\left(\mu_G, \ \sigma_G^2\right)$

for $\qquad 10^{-C} \qquad\qquad C \sim N\left(\mu_C, \ \sigma_C^2\right)$

The induced distribution of A is then also normally distributed, i.e.,

$$-A \sim N\left(\Sigma \mu_i, \ \Sigma \ \sigma_i^2\right) \qquad\qquad (5)$$

where

$$\Sigma \mu_i = \mu_N - \mu_{CE} - \mu_{AE} - \mu_G - \mu_C \qquad\qquad (6)$$

and

$$\Sigma \sigma_i^2 = \sigma_N^2 + \sigma_{CE}^2 + \sigma_{AE}^2 + \sigma_G^2 + \sigma_C^2 \qquad\qquad (7)$$

It is emphasized that the choice of a normal distribution is made here strictly for analytical convenience. For it would be difficult, if not impossible, to justify such a distribution for the parameters involved. This analysis can therefore only serve to clarify relationships rather than provide a defensible quantitative tool.

The purpose of analysis in planetary quarantine implementation is to determine how much control, e.g., sterilization, decontamination, trajectory biasing, etc., needs to be applied in order to assure attainment of the allocation to any one contamination source. Emphasis must therefore be placed on the exponent C, representing the control. The relationship of interest is:

$$C \geq A + N - CE - AE - G \tag{8}$$

This relationship will be examined for a number of cases, depending upon the manner in which the risk allocation, A, is specified.

Case 1: Risk Allocation is the Expected Value $(A \equiv \mu_A)$.

This case assumes that the overall risk allocation to planetary contamination is defined (by COSPAR) as the expected value. Suballocations to a particular mission, and to a particular source within a flight mission, could then be interpreted to also represent an expected value, μ_A.

In this instance it would be sufficient to use mean values for all the parameters and the required amount of control would be

$$C \equiv \mu_C = A + \mu_N - \mu_{CE} - \mu_{AE} - \mu_G \tag{9}$$

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The expected, or mean, value also corresponds to a 0.5 confidence value. The next case considers a specification of confidence values larger than 0.5.

Case II: Risk Allocation Specified with a Confidence Value, A $\equiv$ c_A).

This case assumes that the allocation is to be met with a specified confidence, e.g., the probability that buried organisms on the spacecraft will contaminate the planet is to be 10^{-6}, with 0.99 confidence that this probability will not be exceeded. (Such a specification would have to be based on a confidence value on the overall constraint of 10^{-3} currently defined for the probability that a planet will be contaminated during the period of unmanned exploration.)

To meet the constraint in this form, it would clearly be inadequate to apply the amount of control as given by equation (9). The incremental amount of control, ΔC, would be

$$\Delta C = K_A \sqrt{\Sigma \sigma_i^2} \qquad (10)$$

where:

K_A is the quantile of the normal distribution corresponding to the desired confidence c_A, e.g., for $c_A = 0.99$, $K_A = 2.33$.

The incremental control would therefore be based on the degree of uncertainty in all the parameters, as represented by their variances σ_i^2, and by the desired confidence in the attainment of the allocation, as represented by K_A.

Case III: Risk Allocation Specified with a Confidence $A(c_A)$ but Implemented on the Basis of Individual Parameter Values at a Confidence c_i.

This case is intended to provide the same result for ΔC as in Case II above. However, it is desired to arrive at this result through the use of an appropriate confidence constraint, c_i, in the estimation of individual parameters. Assuming that c_i is to be the same for all parameters,

$$\Delta C = K_i \sum \sigma_i \tag{11}$$

where K_i is the quantile of the normal distribution corresponding to the desired confidence c_i.

Equating (10) and (11) we obtain a relationship between the confidence constraint in individual parameters estimates and the desired confidence in meeting the allocation constraint, as a function of the degree of uncertainty in the parameter estimation process, viz.:

$$K_i = K_A \frac{\sqrt{\sum \sigma_i^2}}{\sum \sigma_i} = \frac{\sqrt{\sigma_N^2 + \sigma_{CE}^2 + \sigma_{AE}^2 + \sigma_G^2 + \sigma_C^2}}{\sigma_N + \sigma_{CE} + \sigma_{AE} + \sigma_G + \sigma_C} \tag{12}$$

The relationships defined herein will be used in the discussion which follows to evaluate various approaches to safety margins in the implementation of planetary quarantine constraints.

5. DISCUSSION

It is evident from the preceding material that any attempt to include the effect of uncertainties in the estimation process invariably leads to the

question of what confidence one wishes to associate with the applied constraints. Although the discussion herein centered around the constraint in the form of an allocation to an individual source of contamination, the confidence value to be associated with it relates to the confidence which one would like to associate with the overall constraint $P_c \leq 10^{-3}$ that a planet will be contaminated during the period of biological exploration. For the individual constraints on sources of contamination derive from the overall constraint through a process of, essentially, administrative suballocations.

In view of the above, it would appear that the desire of the COSPAR Panel on Planetary Quarantine to be able to "defend the assumption that the overall chance of planetary contamination is in fact the value assigned" would require the specification of a confidence value in addition to the upper bound constraint. This is not a practical undertaking, neither from the point of view of credibility of the resultant constraints nor from the point of view of the implementation of such constraints.

There has been relatively little discussion concerning the appropriateness of the magnitude of the overall constraint $P_c \leq 10^{-3}$. The reason for it may well be the fact that the choice of this value must necessarily be quite arbitrary and any value for P_c less than unity would achieve the basic objective of leading to a systematic evaluation of all potential sources of planetary contamination. To superimpose on this arbitrary upper-bound constraint another arbitrary confidence constraint would certainly not make the combined constraints any more credible. For, if the objective was to change the desired risk level, this could simply be done by modifying the value of P_c itself. The only justification for considering an additional confidence constraint would be the desire to facilitate the implementation process. But this is not likely to be the case either.

The subjective nature of the process of estimating individual parameter values has been noted herein and the difficulty of such a process is well known to those involved in it. For example, one might interpret the COSPAR probability constraint to represent an expected value and therefore require all parameters to be estimated at their mean (or median) values, as described in Case I of Section 4. Analytically, this would be an acceptable procedure but practically, it is not. For in all instances when a group of experts are asked to make a subjective estimate of a single probability value, the uncertainties invariably lead them to conservative estimates. The best that can be accomplished under these circumstances is to seek a range of estimates, bounded by conservative and median values as described in Section 3.

Perhaps the most significant aspect of the estimation process is the relative uncertainty in the different parameters, as expressed by the spread between the median and upper bound values. In particular, it is well established that the uncertainty in estimating the probability of microbial growth and proliferation on the planet, P_G, greatly exceeds the uncertainty in all other parameters. This is hardly suprising, for there is relatively little baseline data from which to make the estimate of P_G.

Considerations such as the ones discussed above have led Dr. R. Porter to suggest a method for increasing the amount of control so as to account for the uncertainties in estimation*. Basically, Dr. Porter evaluated the problem in the context of Case II of Section 4. The approach thus requires the selection of a

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*Private communication to Lawrence B. Hall, Planetary Quarantine Officer, NASA, dated 30 September 1971. "Method for Combining Independent Factors in Planetary Quarantine Analyses for Different Confidence Limits."

confidence constraint on the allocation and some estimate of the range of uncertainties in all the parameters so as to compute the differential amount of control, ΔC, to be attributed to our uncertainties.

Referring to equation (10), which formalizes the above relationships, it is evident that a quantitative evaluation is not possible without some further knowledge of the variances σ_i^2 and associated standard deviations σ_i. However, as noted earlier, it is well established that the greatest uncertainties are associated with the parameter P_G. In fact, it is not unreasonable to assume that this latter uncertainty equals or exceeds the sum of the uncertainties in all other parameters of a particular contamination source. Assume, therefore, that

$$\sigma_G = \sigma_N + \sigma_{AE} + \sigma_{CE} + \sigma_C \tag{13}$$

and

$$\sigma_N \approx \sigma_{AE} \approx \sigma_{CE} \approx \sigma_C \tag{14}$$

then

$$\Delta C = K_A \sqrt{\Sigma \sigma_i^2} = K_A \sqrt{\sigma_G^2 + 4\left(\frac{\sigma_G}{4}\right)^2} = 1.12 \, \sigma_G K_A$$

$$\tag{15}$$

or

$$\Delta C \approx \sigma_G K_A$$

The approach taken by the Space Science Board at the Woods Hole evaluation of P_G is, for all practical purposes, based on equation (15). For, by recommending the use of the conservative (0.999 confidence) value of P_G, the desired increment in control would automatically be achieved. The difficulty with this approach is the associated recommendation that this conservatism not be duplicated in the estimation of the other parameter, i.e., in the analytical terms used here, these should be estimated at their mean (0.5 confidence)

values. But, as noted earlier, any group of experts required to do so would, by virtue of the subjective process, still arrive at a conservative estimate.

The above considerations have led to the formulation of Case III in Section 4 in which confidence limits on individual parameters, K_i, are related to the desired confidence in the allocation, K_A. Using the assumptions of equations (13) and (14) in equation (12),

$$K_i = K_A \frac{1.12 \sigma_G}{2 \sigma_G} \approx 0.5 K_A \qquad (16)$$

The table below shows the relationship between the confidence limits c_A and c_i based on equation (16).

Confidence Limit on Allocation — c_A	Corresponding Confidence Limit on Individual Parameters — c_i
0.999	0.95
0.99	0.88
0.95	0.80
0.90	0.74
0.84	0.70

Referring to Figure 3 in which $x(c)/M$ is plotted as a function of the desired confidence limit, c_i, it is evident that the greatest relative effect on the value of x occurs in going from $c_i = 0.99$ or larger, to $c_i \approx 0.85$. Specifying a confidence limit of 0.85 for the estimation of individual parameters would therefore exclude excess conservatism; going below 0.85 would, on the other hand, produce relatively little additional effect.

6. RECOMMENDATIONS

The proposed approach to managing safety margins in the implementation of planetary quarantine requirements is centered around the following fundamental considerations:

(a)   A primary purpose of PQ analysis is to assure systematic and orderly examination of potential sources of contamination.

(b)   Subjective judgments are an essential part of the process. Their integration into decision making — to assure effective utilization of resources, is critically dependent upon a common understanding of the rules and methods used, however arbitrary they may be. Analytical sophistication is therefore most useful when it serves to clarify and systematize these methods.

It is recommended that planetary quarantine analysis continue to be based on the upper-bound constraints currently in use, as derived from the basic COSPAR recommendation that $P_c \leq 10^{-3}$. The addition of confidence limits at this level would not be useful and should therefore be avoided.

Safety margins should be treated at the level of individual parameter estimation, i.e., in arriving at values for the biological populations, attenuating events, conditional events and applied controls.

The manner in which individual parameter values are estimated is critically important. That all available, pertinent factual data needs to be

brought to bear hardly needs emphasis. However, considerable care must also be taken in the selection of experts and in the procedure for applying their expertise to the estimation process. It is clearly desirable to avoid bias due to lack of the particular kind of expertise called for in any one instance.

A distinction must be made between the estimation of the range of a parameter and the selection of a value within this range. The former is a technically based judgment and should be formalized in terms of the median (0.5 confidence) and conservative (0.99 confidence) values as described herein.

The selection of a value within the above range is not a purely quantitative procedure. It can be guided by the use of a 0.85 confidence value, utilizing the relationships of the log-normal distribution. However, this choice must also reflect any other considerations affecting the conservatism of the estimation process, not reflected in its quantitative aspects.